July 28, 2014

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-6050-P
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted electronically via www.regulations.gov (CMS-6050-P)

Re: CMS-6050-P Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items

Dear Sir/Madam:

We are writing to provide comments to the proposed rule CMS-6050-P entitled, "Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items". This proposed rule was published in the May 28, 2014 Federal Register.

Unfortunately, the CMS proposal to institute Medicare prior authorization for prosthetics (as well as a seemingly undefined possible eventual role in orthotics), in the form published on May 28, is not a viable plan that could work for delivery of prosthetic patient care for Medicare amputees. A large proportion of knowledgeable leaders in the prosthetics field say prior authorization should be precluded from any utilization with respect to direct Medicare patient care encounters as provided by physicians, therapists, and licensed/credentialed prosthetic health care professionals.

CMS cites its use of prior authorization in a demonstration project relating to powered wheel chairs. Powered wheel chairs are commodities, shipped in a box as an essentially 'one size fits all' DME item to replace a manual wheelchair. Limb prostheses are not DME—rather they are devices custom fabricated, arising from a series of direct face to face patient encounters/visits, crafted to the unique anatomical features of a specific patient. They replace a missing natural limb providing functional ambulation/mobility. Powered wheelchairs and limb prostheses have virtually nothing in common.

From the perspective of the most important person in the picture, the patient, there is virtually nothing about prior authorization which could benefit the patient in any way. Rather it threatens patients with possible: (a) downgrade of the prosthetic limb they receive; (b) delays in approval, which mean a delay for rehabilitation that will certainly increase co-morbid conditions; and (c) higher out-of-pocket costs if the patient wants a high quality replacement limb. From a beneficiary perspective, the best thing that could happen is for CMS to withdraw this proposal and drop prior authorization for all aspects of direct prosthetic patient care.

How Could CMS Improve this Proposed Rule?

For its Prior Authorization program for prosthetics (and orthotics) to have ANY chance of being workable and palatable for providers, and not dangerous for Medicare amputees, CMS must make significant revisions:

1. **Prior Authorization Must Constitute a Guarantee of Medicare Payment**

Prior authorization needs to constitute a guarantee of Medicare payment. Elimination of Part B RAC and prepayment audits must be the quid pro quo for instituting prior authorization. Requiring providers to undergo prior authorization and then subsequently deny a claim defeats the purpose of prior authorization.

2. **RAC Audits Should Cease Immediately Once Prior Authorization Regulations Are Issued in Final Form**

Once prior authorization regulations are announced as a final rule, RAC audits and prepayment audits of claims across ALL categories of providers must cease immediately.

3. **There Should Be a Threshold for Items to Be Subject to Prior Authorization**

The current proposed threshold of $1,000 is no threshold at all, as it would encompass (and thus subject to prior authorization) every prosthetic limb. Prior authorization should only apply to items that are over a threshold of 167 percent of the average total per patient prosthetic claim by Medicare data for last available year and inflation adjusted to become the current year. Additionally there must be an exclusion for any immediate post surgical and or preparatory prostheses.

4. **There Must Be Certainty in the Prior Authorization Process**

As seen in the PME prior authorization demonstration, CMS has five days to approve or to deny with an explanation. In order to ensure that a decision is made in a timely manner, if a decision has not been made in five days accompanied by specific reference and details of the specific beneficiary (no blanket disapprovals as a matter of CMS delay and convenience), the prior authorization request should be deemed approved and final, so that patient care may proceed.

5. **CMS Must Acknowledge that the Prosthetist's Notes and Records on Patient Visits ARE a Legitimate part of the Medical Record, on the same basis as those of the physician, therapist or other licensed and/or accredited health care provider.**

The prosthetist's clinical documentation specifically functional assessment as it translates into appropriate prosthetic design and component selection are the foundation of his/her education and training. This skill set is unique to prosthetist among all other providers identified as "qualified" in BIPA 427.

Conclusion:

If CMS can make the above five revisions to the proposed rule, then it may be possible to have some constructive discussions if prior authorization could be made palatable for prosthetic care of Medicare amputee patients. In its current form, the Proposed Rule would essentially harm all stakeholders—including prosthetists and our patients.

Thank you for the opportunity to provide comments.

Very truly yours,
Name of Signer & Company